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U.S. Citizenship and Immigration Services
Office of Administrative Appeals MS 2090
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U.S. Citizenship and Immigration Services

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[redacted]

FILE: [redacted] Office: NEBRASKA SERVICE CENTER Date: OCT 0 5 2009

SRC 07 800 23706

IN RE: Petitioner: [redacted]
Beneficiary:

PETITION: Immigrant Petition for Alien Worker as a Member of the Professions Holding an Advanced Degree or an Alien of Exceptional Ability Pursuant to Section 203(b)(2) of the Immigration and Nationality Act, 8 U.S.C. § 1153(b)(2)

ON BEHALF OF PETITIONER:

[redacted]

INSTRUCTIONS:

This is the decision of the Administrative Appeals Office in your case. All documents have been returned to the office that originally decided your case. Any further inquiry must be made to that office.

If you believe the law was inappropriately applied or you have additional information that you wish to have considered, you may file a motion to reconsider or a motion to reopen. Please refer to 8 C.F.R. § 103.5 for the specific requirements. All motions must be submitted to the office that originally decided your case by filing a Form I-290B, Notice of Appeal or Motion, with a fee of $585. Any motion must be filed within 30 days of the decision that the motion seeks to reconsider or reopen, as required by 8 C.F.R. § 103.5(a)(1)(i).

Perry Rhew
Chief, Administrative Appeals Office

DISCUSSION: The Director, Nebraska Service Center, denied the employment-based immigrant visa petition. The matter is now before the Administrative Appeals Office (AAO) on appeal. The AAO will dismiss the appeal.

The petitioner seeks classification pursuant to section 203(b)(2) of the Immigration and Nationality Act (the Act), 8 U.S.C. § 1153(b)(2), as a member of the professions holding an advanced degree. The petitioner seeks employment as a development scientist at Amylin Pharmaceuticals, Inc., San Diego, California. The petitioner asserts that an exemption from the requirement of a job offer, and thus of a labor certification, is in the national interest of the United States. The director found that the petitioner qualifies for classification as a member of the professions holding an advanced degree, but that the petitioner has not established that an exemption from the requirement of a job offer would be in the national interest of the United States.

On appeal, the petitioner submits a brief from counsel and copies of exhibits already in the record.

Section 203(b) of the Act states, in pertinent part:

> (2) Aliens Who Are Members of the Professions Holding Advanced Degrees or Aliens of Exceptional Ability. --
>
> > (A) In General. -- Visas shall be made available . . . to qualified immigrants who are members of the professions holding advanced degrees or their equivalent or who because of their exceptional ability in the sciences, arts, or business, will substantially benefit prospectively the national economy, cultural or educational interests, or welfare of the United States, and whose services in the sciences, arts, professions, or business are sought by an employer in the United States.
> >
> > (B) Waiver of Job Offer –
> >
> > > (i) . . . the Attorney General may, when the Attorney General deems it to be in the national interest, waive the requirements of subparagraph (A) that an alien's services in the sciences, arts, professions, or business be sought by an employer in the United States.

The director did not dispute that the petitioner qualifies as a member of the professions holding an advanced degree. The sole issue in contention is whether the petitioner has established that a waiver of the job offer requirement, and thus a labor certification, is in the national interest.

Neither the statute nor the pertinent regulations define the term "national interest." Additionally, Congress did not provide a specific definition of "in the national interest." The Committee on the Judiciary merely noted in its report to the Senate that the committee had "focused on national interest by increasing the number and proportion of visas for immigrants who would benefit the United States economically and otherwise. . . ." S. Rep. No. 55, 101st Cong., 1st Sess., 11 (1989).

Supplementary information to regulations implementing the Immigration Act of 1990 (IMMACT), published at 56 Fed. Reg. 60897, 60900 (November 29, 1991), states:

> The Service [now U.S. Citizenship and Immigration Services] believes it appropriate to leave the application of this test as flexible as possible, although clearly an alien seeking to meet the [national interest] standard must make a showing significantly above that necessary to prove the "prospective national benefit" [required of aliens seeking to qualify as "exceptional."] The burden will rest with the alien to establish that exemption from, or waiver of, the job offer will be in the national interest. Each case is to be judged on its own merits.

Matter of New York State Dept. of Transportation, 22 I&N Dec. 215 (Commr. 1998), has set forth several factors which must be considered when evaluating a request for a national interest waiver. First, it must be shown that the alien seeks employment in an area of substantial intrinsic merit. Next, it must be shown that the proposed benefit will be national in scope. Finally, the petitioner seeking the waiver must establish that the alien will serve the national interest to a substantially greater degree than would an available U.S. worker having the same minimum qualifications.

It must be noted that, while the national interest waiver hinges on prospective national benefit, it clearly must be established that the alien's past record justifies projections of future benefit to the national interest. The petitioner's subjective assurance that the alien will, in the future, serve the national interest cannot suffice to establish prospective national benefit. The inclusion of the term "prospective" is used here to require future contributions by the alien, rather than to facilitate the entry of an alien with no demonstrable prior achievements, and whose benefit to the national interest would thus be entirely speculative.

We also note that the regulation at 8 C.F.R. § 204.5(k)(2) defines "exceptional ability" as "a degree of expertise significantly above that ordinarily encountered" in a given area of endeavor. By statute, aliens of exceptional ability are generally subject to the job offer/labor certification requirement; they are not exempt by virtue of their exceptional ability. Therefore, whether a given alien seeks classification as an alien of exceptional ability, or as a member of the professions holding an advanced degree, that alien cannot qualify for a waiver just by demonstrating a degree of expertise significantly above that ordinarily encountered in his or her field of expertise.

The petitioner filed the petition on July 27, 2007. The petition included several witness letters. [redacted], the petitioner's doctoral dissertation advisor at New Jersey Institute of Technology (NJIT), stated:

> [U]nder my guidance, [the petitioner] applied his engineering expertise and skills to the development of new methods of studying dissolution testing and dissolution testing equipment, identified several problems with the current design of dissolution testing

equipment, and provided recommendations on how to improve the performance of dissolution testing equipment.

. . . Dissolution testing is a critical analytical method in the stage of formulation design during drug development. . . . Dissolution testing also serves as a required regulatory quality control tool. . . . Failures in drug dissolution testing could have three possible reasons: poor formulation or manufacturing of drug, unreliable performance of the USP [United States Pharmacopeia] Dissolution Test Apparatus II, or both. . . . Not until a few years ago did a small group of researchers begin to conduct fundamental studies to seek the source of the unreliability of the USP Dissolution Test Apparatus II and possible solutions to the problem. [The petitioner] has been one of these pioneer researchers playing a key role in these research efforts. Working on a research project funded by Merck & Co[.], Inc., [the petitioner] has been conducting a comprehensive study on the USP Dissolution Test Apparatus II in order to identify the cause of USP Dissolution Test Apparatus II's inconsistent and unreliable test results.

[The petitioner] contributed significantly to this research field through his development of an innovative approach to study the hydrodynamics of dissolution testing apparatuses that was different from those adopted by most researchers. . . . Such information is critical to advancing our fundamental understanding of the dissolution rate process, enhancing the reliability of dissolution testing, and eliminating artifacts associated with test equipment.

[redacted] Associate Director of Pharmaceutical Development at Merck & Co., Inc., collaborated with the petitioner and [redacted] [redacted] called the petitioner's "findings . . . highly valuable for current users of the USP Dissolution Test Apparatus II." Regarding the petitioner's current work, [redacted] stated: "My understanding is that he participates in the development of an innovated diabetes drug."

[redacted] stated: "I am aware of [the petitioner's] research through his presentations and publications even though I have not worked with him personally." (The record shows that [redacted] has collaborated with [redacted] the two share several author credits.) [redacted] credited the petitioner with "several significant contributions to our understanding of the hydrodynamics of the [U]SP Dissolution Test Apparatus II." [redacted] stated that the petitioner "is among the pioneers in this area." [redacted] did not comment on the petitioner's more recent work at Amylin.

[redacted], Senior Research Scientist at Canada's Bureau of Pharmaceutical Sciences, stated that the petitioner's "efforts . . . are highlighting problems [a]ffecting current dissolution practices. His experimental studies will provide improved understanding of the issues which then will lead to the solutions for the problems." [redacted] letter is dated several months after the petitioner left NJIT. [redacted] did not state how the petitioner's post-NJIT work related to dissolution problems.

[redacted], formerly of the USP, stated that the petitioner's "innovative findings . . . enhanced our understanding dramatically of hydrodynamics effects on dissolution test results." Regarding the petitioner's current work at Amylin, [redacted] states only that it relates to diabetes drugs.

[redacted], a Research Scientist at the U.S. Food and Drug Administration (FDA), stated that the petitioner's "research points out the direction for improving the USP Dissolution Test Apparatus II." [redacted] stated that the petitioner now works "on development of the first once-a-week diabetes drug, Exenatide LAR," but did not elaborate as to the nature of that work. [redacted] stated that the petitioner's "research is indispensable to the success of improving dissolution testing," but did not explain how the petitioner's work at Amylin relates to the improvement of dissolution testing.

[redacted], Senior Research Investigator at Bristol-Myers Squibb and one of the petitioner's collaborators, stated that the petitioner's "original findings are highly valuable for the current users of the USP Dissolution Apparatus II," and that the petitioner "is now participating in the development of Exenatide LAR, the first once-a-week drug for diabetes in the world. . . . It is currently in phase 3 clinical studies." This letter, like the other letters, leaves open the nature of the petitioner's exact role in developing the drug. Given that the petitioner joined Amylin only a few months before this letter was written, and Exenatide LAR is already in phase 3 clinical studies, it does not appear that the petitioner was at Amylin at the time the company first formulated the drug.

The petitioner's own résumé contains this description of his work at Amylin:

> Initiate and support sustained-release formulation development and manufacturing process development studies for proteins/peptides in Amylin's pipeline; plan and schedule development work according to department's and company's timetables and establish short and long term goals to meet project timelines; assist in maintaining laboratory instrumentation and inventories of chemicals and reagents; maintain accurate and complete laboratory notebooks; and participate in decision-making process regarding development priorities of the group.

The petitioner submitted copies of articles based on his doctoral studies. He did not claim independent citation of these articles, or state that his work at Amylin would produce further publications.

On September 10, 2008, the director instructed the petitioner to submit evidence of his "influence on [his] field." The director specifically requested evidence that other researchers have cited the petitioner's published work.

In response, the petitioner documented one citation of his work. Counsel stated "the lack of citations should not detract from the impressiveness of [the petitioner's] research and impact [on] the field."

Several witness letters accompanied the petitioner's response to the notice. [redacted] stated that few researchers are engaged in hydrodynamic study of the USP Dissolution Test Apparatus II, so the low citation rate of the petitioner's work "is quite understandable," although [redacted] predicted

the appearance of "many more citations of [the petitioner's] research in the near future." Prof. [redacted] asserted that it takes time for citations to follow the publication of an influential article. We do not dispute this assertion, but the petitioner must still establish the impact and influence of his work. The petitioner is not exempt from this requirement simply because he filed his petition before such citations had time to appear. Also, [redacted] claims do not require us to presume that the petitioner's work will be heavily cited in the future.

Counsel is correct that citations are not the only conceivable gauge of the petitioner's impact, although they do have the advantage of existing objectively and independently of the petition. If there is no documented reaction to a researcher's influence until that researcher requests letters discussing his work, it is reasonable to question the true extent of that influence. In the petitioner's case, witnesses have very heavily emphasized his studies of the USP Dissolution Test Apparatus II. Therefore, in the absence of heavy citation of his work, a good gauge of the petitioner's influence would be to see how much the petitioner's work has affected the use or design modifications of the USP Dissolution Test Apparatus II. If the petitioner cannot show any such changes in the apparatus' use or design, then it is not clear how the petitioner could be said to have had influence relating to the apparatus. (Being among the first to study a particular problem is not, by itself, influence or impact within a given field.) With this in mind, we examine the second group of witness letters.

Six independent witnesses all discussed the petitioner's work with the USP Dissolution Test Apparatus II. None of the witnesses indicated that the petitioner continues such work, and the record contains nothing from Amylin to indicate that the petitioner continues to work on this problem. Given that the record strongly suggests that the petitioner no longer concentrates his work on the USP Dissolution Test Apparatus II, we will not entertain the argument that the petitioner's continued presence in the United States is required for further progress on such studies. We will consider evidence of the impact of the petitioner's past work, but his work in this area has already been published and will continue to be available to researchers regardless of whether the petitioner remains in the United States in the future.

[redacted] of Life Science at Simulations Plus, Inc., Lancaster, California, stated that the petitioner "is clearly a pioneer in the field of hydrodynamic study on the USP Dissolution Test Apparatus II. . . . His numerous past discoveries of major significance leave little doubt that [he] will continue to make even more important breakthroughs in the area of pharmaceutical research and development."

[redacted] of the FDA's Office of Generic Drugs stated that the petitioner's "research findings have resulted in a significant impact on the drug dissolution test field. . . . His pioneering work, cutting-edge findings, and significant achievements in his field have been highly acclaimed and widely accepted by the international scientific community." [redacted] did not elaborate on what those findings are, or how they have been "widely accepted," except to state that the petitioner showed that the "apparatus is extremely sensitive to the operating conditions." [redacted] stated that the petitioner's work with simulations "opens the door for making the dissolution test unnecessary in the future," but did not indicate that the FDA is considering eliminating the dissolution test requirement.

[redacted] of Latitude Pharmaceuticals, San Diego, stated that the petitioner's "original findings are highly valuable for current users of the USP Dissolution [Test] Apparatus II and very helpful to eliminate dissolution testing variability." [redacted] stated: "We have enhanced our productivity and shortened our product development cycle by applying [the petitioner's] research findings into our projects." Regarding the petitioner's more recent work at Amylin, [redacted] stated:

> [The petitioner] successfully reduced the residual silicone oil amount in the formulation of Exenatide LAR to an accepted level. He optimized [the] Exenatide LAR injection device to ease the administration of the drug product. He [has] developed [a] high yield sieving process of the Exenatide LAR powder to reduce the needle clogging rate during injection. He is developing a high throughput filling process for the final Exenatide LAR product, which consists of drug powder and diluent. . . . [The petitioner] is challenging science to bring this new drug to the patients as quickly as possible.

[redacted] Senior Principal Scientist at Pfizer, Inc., in the United Kingdom, asserted that the petitioner "has gained international acclaim" for his work with the USP Dissolution Test Apparatus II. [redacted] asserted that the petitioner's "research work and findings have been invaluable to my own work." [redacted] is the author of the sole submitted paper that cited the petitioner's work.

[redacted] of the University of Iowa stated that the petitioner "is among the very few pioneering scientists to have had a substantial impact in research to characterize the hydrodynamics and to identify its effects on drug dissolution testing." He is one of several witnesses to assert that the petitioner's findings were reported to the FDA in 2005, but the record does not show what action, if any, the FDA has taken in the years since the report. (The petitioner did not write the report, but the report's authors, [redacted], used their past work with the petitioner as source material.)

[redacted] Director of Analytical Development at Conor Medsystems, LLC, stated:

> I would rate [the petitioner] as a top research scientist for his outstanding contributions in his field. Although I have never personally worked with him, I reviewed [the petitioner's] research paper manuscript titled "Hydrodynamic Investigation of USP Dissolution Test Apparatus II" in 2006 and suggested its acceptance for [publication in the] *Journal of Pharmaceutical Sciences*. . . .
>
> [The petitioner] found that although the working volume of the USP Dissolution Test Apparatus II tank is small and the impeller rotation speed is low, the hydrodynamics in the bottom region of this tank is extremely complicated. This is the most critical region, because the drug tablet under test stays in this region during the dissolution test. . . . [A] small variation in the location of the tablet on the tank bottom . . . [is] very likely to result in significantly different velocity gradients and shear strain rates experienced by the tablet. This phenomenon first discovered by [the petitioner] introduces huge variability into the dissolution test results generated by the USP Dissolution Test

> Apparatus II. . . . The ultimate solution of this problem is to redesign this analytical equipment, where [the petitioner's] research findings will provide critical guidance and direction in these efforts.

The petitioner submitted nothing from the USP or any other governmental or industry body to indicate that the petitioner's work has, in fact, led to efforts to redesign the USP Dissolution Test Apparatus II.

An updated version of the petitioner's résumé indicated that he uses "Computational Fluid Dynamics (CFD) to develop and optimize drug delivery devices for different drug candidates in Amylin's pipeline."

The director denied the petition on January 21, 2009, citing the petitioner's "modest publication record" and minimal citation of the petitioner's work. The director acknowledged the petitioner's witness letters, but stated that if the petitioner's contributions were especially significant, then there would be some evidence of their importance other than witness letters solicited to support the petition.

On appeal, counsel asserts that the previously submitted witness letters "not only attest to the recognized importance and impact of [the petitioner's] research results [in] the field of drug discovery research, but also to their implementation in laboratories and companies around the world." The record does identify individuals who have put the petitioner's findings to use, but the record does not show that their statements represent anything approaching a consensus or widespread implementation in the field.

Counsel asserts that the petitioner's "findings . . . have since been passed on to the FDA as recommendations for possible improvements to the apparatus," but the petitioner has submitted nothing from the FDA to show that that the FDA has taken any concrete action on those recommendations, or that the petitioner's work has resulted in any implemented improvements to the USP Dissolution Test Apparatus II. The petitioner has submitted letters from two FDA researchers, but he has not shown that either of those officials has the authority to implement the petitioner's findings. The letters do not amount to institutional notice of the petitioner's work.

Counsel attempts to explain the petitioner's low citation rate by stating: "The pharmaceutical industry is a highly competitive industry and as a result, researchers in pharmaceutical companies tend to file patents on their findings and results rather than journal papers in order to protect their companies' proprietary findings." This assertion seems to be off-point, however, because the petitioner's principal contribution does not involve the private intellectual property of any one pharmaceutical company. Rather, it concerns (in counsel's words) "a critical instrument that is widely used in the pharmaceutical industry." Counsel's explanation is also at odds with prediction of "many more citations of [the petitioner's] research in the near future." With respect to counsel's claim that pharmaceutical companies rely on patents rather than journal publications, the record contains no evidence of any patents or patent applications resulting from the petitioner's work.

The record shows that the USP Dissolution Test Apparatus II was already known to produce questionable results at times, well before the petitioner began his research. The record does not indicate

that the petitioner's work has yielded any improvements to the apparatus. At best, some witnesses assert that the petitioner's work points the way to eventual future improvements, even though the FDA and USP remain institutionally silent on the matter.

Furthermore, there is no indication that the petitioner continues to work on improvements to the apparatus. That work appears to be focus, with which the petitioner was temporarily involved owing to his doctoral studies in laboratory. If the petitioner no longer works directly on the problems with the USP Dissolution Test Apparatus II, then there is no reason to believe that holding the petitioner to the labor certification requirement will delay or hamper continued progress in such research.

The petitioner had already left NJIT for Amylin before he filed the petition, but the record contains little evidence about that work, except to indicate that the petitioner participates in efforts to refine an already-developed drug. His claimed reputation appears to rest not on a sustained series of contributions, but on his now-completed Ph.D. program. The petitioner has not met his burden to establish that his ongoing work will continue to have the same impact as what he was previously doing in the laboratory of an already-established university professor.

As is clear from a plain reading of the statute, it was not the intent of Congress that every person qualified to engage in a profession in the United States should be exempt from the requirement of a job offer based on national interest. Likewise, it does not appear to have been the intent of Congress to grant national interest waivers on the basis of the overall importance of a given profession, rather than on the merits of the individual alien. On the basis of the evidence submitted, the petitioner has not established that a waiver of the requirement of an approved labor certification will be in the national interest of the United States.

The burden of proof in these proceedings rests solely with the petitioner. Section 291 of the Act, 8 U.S.C. § 1361. The petitioner has not sustained that burden.

This decision is without prejudice to the filing of a new petition by a United States employer accompanied by a labor certification issued by the Department of Labor, appropriate supporting evidence and fee.

ORDER: The appeal is dismissed.